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| 08/732,408 | 12/09/96 | REINMULLER | J | HUBR1099PFFM |

FELFE AND LYNCH
805 THIRD AVENUE
NEW YORK, NY 10022

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EXAMINER

KOH, C

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 21

Application Number: 08/732,408
Filing Date: December 9, 1996
Appellant(s): Reinmuller

James R. Crawford
For Appellant

EXAMINER'S ANSWER

MAILED
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This is in response to appellant's brief on appeal filed November 29, 1999.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

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(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement of the grouping of claims in the brief is correct.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

| | | |
|-----------|-------------|---------|
| 5,358,521 | SHANE | 10-1994 |
| 5,496,368 | WIESE | 3-1996 |
| 5,676,146 | SCARBOROUGH | 10-1997 |

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 5, 11-14 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shane (5,358,521). This rejection is set forth in prior Office action, Paper No. 11 .

In addition to the above, Shane discloses a multi-layer prosthesis which simulates tissue tactility by structuring the plurality of layers of material making up the prosthesis to include lubricant coating between the layers. Shane further teaches that it is the plurality of layers and the lubricity of their movement which contributes greatly to the tactile simulation of human tissue (see Abstract; col. 8, lines 24-30). Therefore, the layers in the implant taught by Shane must also be displaceable one against the other as set forth in the claims as amended.

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Claims 6-10 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shane (5,358,521) as applied to claim 1 and further in view of Wiese (5,496,368). This rejection is set forth in prior Office action, Paper No. 11.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shane (5,358,521) as applied to claim 1 and further in view of Scarborough. This rejection is set forth in prior Office action, Paper No. 11.

(11) *Response to Argument*

Applicant argues that Shane discloses a prosthesis essentially consisting of a fluid filled lumen which contributes most of the bulk of the prosthesis. This is partially correct because the presence of a plurality of layers having a lubricant between the layers in Shane's prosthesis is also essential to give the prosthesis implant the lubricity of their movement which contributes greatly to the tactile simulation of human tissue (col. 8, lines 23-30).

Applicant further states that a fluid filled lumen is not present in accordance with the implant of the present invention. However, the term "comprising" in the claimed invention does not exclude such lumen which contributes mass and enhanced motility to the prosthesis.

The purpose of including such fluid filled lumen in Shane's implant is to provide volume to the implant because the implant is for the reconstruction of soft tissue such as breast which requires volume.

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However, Shane additionally teaches that their prosthesis finds ready use in the augmentation or restructuring of the human breast as well as in cosmetic modification of other portions of the anatomy as, for example, the chin, the pectorals, etc. (Col. 8, lines 32-36).

Therefore, depending on the tissue to be reconstructed, one of ordinary skill in the art can easily control the amount of volume added to the implant, even to the extent that a fluid filled lumen is excluded from the breast implant exemplified by Shane to obtain an implant intended for the construction of soft tissues that do not require additional volume in light of various uses taught by Shane.

With respect to the volume of the implant of the present invention contributed by the layers, i.e. a plurality of thin pliable structural elements, applicant argues that the volume of the implant is contributed by the layers of thin elements having a thickness of 10-200 micrometer, not by a fluid. Applicant further state that the lubricant only fills the capillary gaps between the individual layers and makes only slight contribution to the filling volume.

Although a fluid filled lumen in Shane's implant contributes bulk of the prosthesis because of the specific type of the implant that requires such bulk, the volume contributed by a plurality of structural elements in the instant invention does not distinguish from the volume contributed by the multiple-layers in the prosthesis implant taught by Shane, because Shane also teaches that the lubricant present between the layers is insufficient in quantity to inflate the lumen between the layers and instead is a volume selected to provide a thin coating of lubricant sufficient for inhibiting direct contact of said layers (col. 8, lines 55-64).

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Therefore, the volume contributed by the layers and the lubricant therebetween is also expected to be only slight.

With respect to applicant's argument based on foldability of the structural elements in the instant case as opposed to the layers in Shane's implant, it is based on unclaimed subject matter, because none of the claims reflect that the structural elements are folded.

As to the thickness of the layers or structural elements, even though Shane does not explicitly teach the thickness in the range claimed, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the pliable layers to obtain the implant having desired properties depend on the type of implant for the intended purpose.

Each of the secondary references of Wiese or Scarborough is used for its specific teachings of specific limitations variously set forth in dependent claims and do remedy the deficiencies of Shane as discussed in the previous office action of Paper No. 11.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Choon P. Koh
Choon P. Koh
January 28, 2000

Confessee:
David H. Willse
David H. Willse
Primary Examiner

Mickey Yu
Mickey Yu
Supervisory Patent Examiner
Group 3700

666 Fifth Avenue
New York, NY 10103